

REMARKS

I. Status of the Claims

Claims 1-112 were previously canceled. Upon entry of the present amendment, claims 126-144 are further canceled for being directed to a non-elected invention. Claim 116 is rewritten to an independent claim. Thus, claims 113-125 remain pending. The Examiner has indicated the allowability of claim 115, except for its dependency from a rejected claim.

II. Objection to the Specification

The specification is amended to delete reference to a browser-executable code. No new matter is introduced. The Examiner's objection to the specification on this basis is thus addressed.

III. Claim Objection and Rejection

A. Claim Objection

The Examiner objected to claim 116, alleging improper dependent form. As amended, claim 116 has been rewritten into an independent claim. This objection is thus obviated.

B. 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 113, 114, and 116-125 under 35 U.S.C. §112, first paragraph, for alleged failure to meet the written description requirement. Specifically, the Examiner objected to the new limitation of "at least 90% identity to SEQ ID NO:6" introduced by Applicants' previous amendment and invited Applicants to identify in the specification support for a method for eliciting or enhancing an immune response against HER-2/Neu protein by administering a polypeptide comprising a HER-2/neu fusion protein that is at least 90% identical to SEQ ID NO:6.

Applicants contend that the specification as originally filed fully supports the element of "at least 90% identity to SEQ ID NO:6" and the claimed method. First of all, the specification describes the concept of "percentage of sequence identity" on page 9, lines 18-26,

where it is stated that, "[t]he percentage is calculated by determining the number of positions at which the identical *nucleic acid base or amino acid residue* occurs in [the comparison sequence and the reference sequence]... (emphasis added)" This language clearly indicates that the term of "percentage sequence identity" can be used to refer to the similarity of either a polynucleotide sequence or an amino acid sequence to a reference sequence.

Secondly, on page 10, lines 4-6, the specification states,

"Substantial identity" of amino acid sequences for these purposes normally means sequence identity of at least 40%. Preferred percentage sequence identity of polypeptides can be integer from 40% to 100%. More preferred embodiments include at least 60%, 65%, 70%, 75%, 80%, 85%, 90%, 95%, or 99%.

Because of the context in which this description is found, one of skill in the art reading this paragraph would immediately understand that these recited percentages refer to the sequence percentage identities of a polypeptide to a reference amino acid sequence, such as SEQ ID NO:6. Thus, Applicants submit that the limitation of "at least 90% identity to SEQ ID NO:6" added by the previous amendment is fully supported by the specification as filed.

Thirdly, the specification states that the invention relates to HER-2/neu fusion proteins, compositions comprising the fusion proteins, and method for eliciting or enhancing an immune response to HER-2/neu protein by administering such compositions. See specification on page 3, lines 5, 9-14, and 22-25. In describing the concept of "HER-2/neu fusion protein," the specification states that "variants" are encompassed in this term. See, *e.g.*, page 7, lines 26-29. In turn, the term "variant" is described as "substantially identical" or "substantially similar" to "a fusion protein comprising native [HER-2/neu] polypeptide components." See, *e.g.*, page 8, lines 4-6. Since SEQ ID NO:6 is the amino acid sequence of a direct fusion protein of human HER-2/neu ECD and PD, one of skill in the art would understand upon reading this description that the specification indeed teaches a method for eliciting or enhancing an immune response against HER-2/Neu protein by administering a polypeptide comprising a HER-2/neu fusion protein that is "substantially identical," *e.g.*, at least 90% identical, to "a fusion protein comprising native [HER-2/neu] polypeptide components," *e.g.*, SEQ ID NO:6.

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PATENT

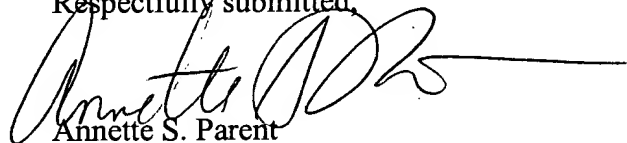
As such, the withdrawal of the written description rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,


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